REMARKS

Favorable reconsideration of this application, in light of the preceding amendments and following remarks, is respectfully requested.

Claims 1, 3-4, 6, 8-12 and 23-25 are pending in this application. Claims 1, 8-9 and 12 are amended and claims 2, 5, 7 and 13-22 have been cancelled. Claims 23-25 have been newly added. Claim 1 is the sole independent claim.

Applicants respectfully note that the present action does not indicate that the claim to foreign priority under 35 U.S.C. §119 has been acknowledged or that certified copies of all priority documents have been received by the U.S.P.T.O. Applicants respectfully request that the Examiner's next communication include an indication as to the claim to foreign priority under 35 U.S.C. §119 and an acknowledgement of receipt of the certified copies of all priority documents.

Applicants also respectfully note that the present action does not indicate that the drawings have been accepted by the Examiner. Applicants respectfully request that the Examiner's next communication include an indication as to the acceptability of the filed drawings or as to any perceived deficiencies so that the Applicants may have a full and fair opportunity to submit appropriate amendments and/or corrections to the drawings.

New Claims

By the present Amendment, Applicants submit that claims 23-25 have been added. Support for new claims 23-25 can be found in at least in the Specification as originally filed. In particular, support for claims 23-25 can be found at least on page 5, lines 18-25 and page 6, lines 1-5. As such, Applicants submit that no new matter has been added.

Rejections under 35 U.S.C. § 112

Claims 1-6 and 8-12 stand rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for constructing HBsAg particles, allegedly does not reasonably provide enablement for making any other nanoparticles containing any undefined molecules, and does not reasonably provide enablement for using uncharacterized nanoparticles containing any undefined molecules as a drug. Applicants respectfully traverse this rejection for the reasons detailed below.

Claims 2 and 5 have been cancelled, and so, the rejection of claims 2 and 5 is now moot.

In particular, the Examiner asserts that since there are allegedly no structural limitations to a particle-forming protein and a substrate and displaying molecule in claim 1, the scope of the claims encompass drugs containing "any nanoparticles" that contain "any substances".

Applicants submit that the amendments to claim 1 should provide structural limitations to the particle-forming protein, substrate and displaying molecule disclosed in independent claim 1. Applicants also submit that independent claim 1 is supported by examples described in the specification, but in particular, page 5, lines 18-24.

The Applicants submit that the specification is enabling and respectfully request that the rejection to Claims 1-6 and 8-12 under 35 U.S.C. § 112 be withdrawn.

Example Embodiments of the Present Application

Independent claim 1 recites a drug, comprising a substance to be transferred into a cell for treatment of a disease encapsulated in a hollow nanoparticle containing a particle-forming protein, the nanoparticle displaying a molecule, which binds with a particular molecule on a cell surface, wherein the molecule which binds with the particular molecule on a cell surface is selected from the group consisting of epidermal growth factors, interleukin, interferon, colony stimulating factors,

tumor necrosis factors, transforming growth factor β, platelet-derived growth factors, erythropoietin, Fas antigens activin, bone morphogenetic factors, and nerve growth factors, the protein is a modified hepatitis B virus surface antigen protein, and the substance to be transferred into a cell is thymidine kinase (HSV1 tk) gene of herpes simplex virus type 1. Example non-limiting embodiments of this feature are discussed, for example, on page 5, lines 18-24 of the instant specification.

The drug of example embodiments enables effective treatment of diseases of particular cells or tissues through a simple method of intravenous injection and improves on conventional treatment in that it does not require administration of a relatively large amount of drugs or surgery as in gene therapy. The drug of example embodiments also has relatively little chance of side effects and is applicable in clinical practice. For example, the HSV1 tk gene of example embodiments can be transferred to human squamous cell carcinoma with improved specificity and efficiency.

Rejections under 35 U.S.C. § 102

Claims 1 and 6 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Rosenfeld (1997; Annals of Surgery 1997; 225(5): 609-618). Applicants respectfully traverse this rejection for the reasons detailed below.

Referring to pp. 610-611 and 614-615 of Rosenfeld, the Examiner alleges that Rosenfeld discloses an adenoviral comprising HSV1 tk gene (AdCMVHSV-1tk) and that Ad/HSV-1tk particles are highly transducible to human pancreatic carcinoma cells. The Examiner further states that the resulting carcinoma cells expressing HSV-1 tk protein is more sensitive to chemotherapy agent ganciclovir (GCV). Since AdCMVHSV-1tk particle is a nanoparticle which contains a particle-forming protein, and displays a molecule that binds with a particular molecule on a cell surface, wherein the HSV-1 tk substance transferred into a cell can be used for

treatment of a cancer, Rosenfeld's AdCMVHSV-1tk particles meet the structural limitations in the claims. Applicants respectfully disagree.

Applicants respectfully submit that amended, independent claim 1 is neither anticipated by nor rendered obvious over Rosenfeld. In particular, the Examiner fails to point out where Rosenfeld teaches the molecule which binds with a particular molecule on a cell surface as recited in independent claim 1. Therefore, Rosenfeld does not appear to teach nor suggest "the hollow nanoparticle displaying **a molecule which binds with a particular molecule on a cell surface**" as recited in independent claim 1.

The Applicants, therefore, respectfully request that the rejection to Claims 1 and 6 under 35 U.S.C. § 102(b) be withdrawn.

Claim 6, dependent on independent claim 1, is patentable for the reasons stated above with respect to claim 1 as well as for their own merits.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection to independent claim 1 and all claims dependent thereon.

Furthermore, newly-added claims 23-25 are also allowable over Rosenfeld, at least by virtue of their dependency on independent claim 1.

Double Patenting

Claims 1-6 and 8-12 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claim 1 of 10/509,247, Claims 107 of 10/509,252, and Claims 28, 30, 31, 33, 36, 37 and 40 of co-pending application 10/220,125. Applicants respectfully traverse this rejection for the reasons detailed below.

Claims 2 and 5 have been cancelled, and so, the rejection of claims 2 and 5 is now moot.

The amendments to independent claim 1 include features for which no double patenting issue is raised regarding co-pending applications 10/509,247, 10/509,252, and 10/220,125. The Applicants, therefore, respectfully request that the rejection to 1-6 and 8-12 on the ground of nonstatutory obviousness-type double patenting be withdrawn.

Furthermore, Applicants cannot remedy this rejection at this time and request that this rejection be held in abeyance. This is because none of the co-pending applications has matured into a patent. Should all outstanding issues in the present application be resolved save for the double-patenting rejection, and should none of the co-pending applications have by such time matured into a patent, then the Examiner should allow the instant application and thus any double patenting rejection should attach to the above-noted co-pending applications.

CONCLUSION

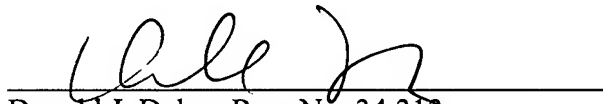
In view of the above remarks and amendments, the Applicants respectfully submit that each of the pending objections and rejections has been addressed and overcome, placing the present application in condition for allowance. A notice to that effect is respectfully requested. If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to contact the undersigned.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Erin G. Hoffman, Reg. No. 57,752, at the telephone number of the undersigned below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 08-0750 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

HARNESS, DICKEY, & PIERCE, P.L.C.

By 

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